

# EXHIBIT 5



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September 15, 2004

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VIA FACSIMILE

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Re: *Amgen, Inc. v. Columbia University litigation, MDL-1592*

Dear Counsel:

Thank you for David Gindler's letter today inviting additional clarification of the Covenant. Plaintiffs request further clarification of the Covenant in seven categories:

1. "any product currently made, used, offered for sale, sold, or imported, or any product that was made, used, offered for sale, sold, or imported" (Covenant), and "by way of example, Rituxan is a product currently made and sold by Genentech" (Letter, Sept. 10, 2004). Please confirm:

(a) The Covenant extends not only to vials or lots that were manufactured by September 1, 2004, but also to vials or lots of the same product manufactured at any time in the future, and to the use and sale of such material.

(b) The Covenant extends to all proteins now sold (rituximab, epoetin alfa, etanercept, etc.), not merely the brand name products marketed.

(c) The Covenant extends to all proteins now sold, even if changes are later made in the process by which such a protein is manufactured.



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(d) The Covenant extends to all proteins now sold, even if a new construct or new transformed cells are later created to express any such protein.

2. The Covenant refers to "any product." The '275 patent refers to transformed cells (e.g., '275 patent, claim 1), constructs (e.g., '275 patent, claim 20) and methods (e.g., '275 patent, claim 14). Please confirm:

(a) The Covenant extends to all transformed cells made by September 1, 2004, whether or not amplification of DNA I or DNA II has occurred.

(b) The Covenant extends to all constructs made by September 1, 2004.

(c) The Covenant extends to all proteins expressed before September 1, 2004 using such transformed cell or construct or method.

(d) The Covenant extends to the continued production, use or sale after September 1, 2004, of such cells, constructs and proteins.

3. "The issue of new products" (RT 9/9/04, 29:24). Please confirm:

(a) The Covenant extends to the future manufacture, use, sale, etc. of anything a plaintiff had produced by September 1, 2004, such as a transformed cell, a construct, or a cell line that had been made by September 1, 2004, regardless of whether that thing had yet led to any commercially sold product.

(b) As an example, the Covenant extends to the future manufacture, use, sale, etc. of a protein that a plaintiff had made by September 1, 2004, or of a construct, transformed cell, or cell line expressing that protein, where the protein was in pre-clinical or clinical trials on that date.

4. "prior to the date of this covenant" (Covenant).

Please confirm that, if a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant extends to:

- (a) such construct or cotransformed cell.
- (b) methods using such construct or cotransformed cell.
- (c) a protein produced using such construct or cotransformed cell.



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5. "This covenant is limited to the '275 patent as it presently reads and does not apply to any other patent, whether related or unrelated to the '275 patent. Specifically, this covenant does not apply to any reissued or reexamined version of the '275 patent that may issue in the future or to any patent that may issue from United States Patent Application No. 08/477,159" (Covenant). "The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads" (Letter, Sept. 10, 2004). "The Covenant does not apply to any claim in any patent that may issue in the future based upon the pending '159 application, irrespective of whether plaintiffs contend that such claim is the same as, or substantially identical to, a claim of the '275 patent as it currently reads" (*Id.*). Please confirm:

(a) The September 10, 2004 letter was a modification (not merely a "clarification") of the Covenant, in stating that "The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads."

(b) The Covenant extends to any claim in any patent that may issue in the future based upon the pending '159 application, if that claim is actually (not merely "contended" to be) identical or substantially identical to a claim of the '275 patent as it currently reads.

(c) Other than the '159 application and the '275 reissue, no pending patent applications exist that claim priority to U.S. Application Serial No. 06/124,513.

6. "The Covenant does not apply to [plaintiffs'] affiliates or customers" (Letter, Sept. 10, 2004). Please confirm that a plaintiff's rights under the Covenant are transferable by the plaintiff with the product. In other words, please confirm that the Covenant applies to a covered product if, for example, a plaintiff elects to have the product manufactured for it by an affiliate or third party, or sold by an affiliate or third party. Similarly, please confirm that the Covenant applies to a covered product if a plaintiff sells its business in the product to a third party.

7. Columbia "covenants . . . not to assert any claim of patent infringement" (Covenant). Please confirm that this extends to activity by a plaintiff that could be considered to be contributory infringement or inducement of infringement of the '275 patent.

Sep-15-2004 04:08pm From-PILLSBURY-WINTHROP LLP

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Plaintiffs would appreciate Columbia's written confirmation on these points as soon as possible tomorrow, and no later than 5:00 pm PST. If you would like to discuss these issues, please let us know when.

Very truly yours,

Kirke M. Hasson

cc: All plaintiffs' counsel